



Food and Drug Administration Southwest Import District Southwest Region 3310 Live Oak Street Dallas, Texas, 75204

Telephone: 214-655-5310 FAX: 214-655-5330

WARNING LETTER

Ref: 2001-SWID-WL-3

March 5, 2001

FEDERAL EXPRESS

G Products, Inc. Alain Guizar, Owner 3235 Hancock St. San Diego, CA 92110

Dear Mr. Guizar:

On February 7, 2001 we attempted to examine three shipments of avocado pulp products identified with entry numbers G59-0015944-5/1/2A; G59-0016235-7/1/1; and G59-0016325-6/1/1 that were being detained by the Food and Drug Administration (FDA). The shipments were offered for import (imported) into the United States by your firm on December 4, 2000, January 16, 2001 and January 29, 2001. As explained in our detention notices, these entries were being detained because they were found (by FDA laboratory analysis) to be contaminated with Listeria monocytogenes, a pathogenic microorganism that may render this product injurious to health. When we attempted to examine these shipments at San Diego Cold Storage, National City, CA, the location you identified as the place of storage, the product was not present and your firm has not been able to locate these products. This is a violation of 21 USC 381(a) and 21 CFR Section 1.90 which requires that the importer hold an imported article and not distribute it pending receipt of the results of examination of a sample.

Furthermore, on January 26, 2001, during a telephone conference call with FDA Compliance Officer Vincent Iacono, Supervisory Investigator Robert Rast, and Investigator Patty Walters you admitted to exporting to Mexico (22) shipments of avocado pulp products without notifying FDA or U.S Customs. The shipments were under detention without physical examination because they may be contaminated with Listeria monocytogenes and were identified with entry numbers G59-0016057-5; G59-0016065-8; G59-0016091-4; G59-0016105-2; G590016117-7; G59-0016122-7; G59-0016127-6; G59-0016136-7; G59-0016146-6; G59-0016152-4; G59-0016161-5; G59-0016163-1; G59-0016172-2; G59-0016184-7; G59-0016187-0; G59-0016189-6; G59-0016195-3; G59-0016201-9; G59-0016206-8; G59-0016216-7; G59-0016221-7; and G59-0016233-2. Because the alleged exportations were accomplished without notifying the FDA and or U.S. Customs, officials of either agency were not afforded the opportunity to witness and verify the exportation.

We are concerned with your apparent disregard to our Notices of FDA Action especially after advising you of the requirements to hold product via FDA Notices of Action and during several meetings and telephone conversations with our Investigators and Compliance Officer.

As a result, we have recommended that the U.S. Customs Service require that future shipments of food imported into the U.S. by your firm be held in secured storage. If required, secured storage will be under the supervision and direction of U.S. Customs, such as in a bonded warehouse. You will be responsible for all costs incurred at secured storage.

In addition, we have requested U. S. Customs Service to order redelivery of the shipments.

Within 15 working days of receipt of this letter, notify this office in writing of the specific steps you have taken to correct this violative situation, including an explanation of each step being taken to prevent recurrence.

Your reply should be addressed to: Vincent F. Iacono, Compliance Officer

U.S.Food and Drug Administration

Otay Mesa Port of Entry 9777 Via De La Amistad #131

San Diego, CA 92154

Should you have any questions related to this letter, you may also contact Mr. lacono at 619-661-3273 ex 229.

Sincerel

Robert J. Deininge Southwest Import District Director

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